IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ALKEM LABORATORIES LIMITED Plaintiff, v. NPS PHARMACEUTICALS, INC. Defendant.	)	Civil Action No. 1:13-cv-06487

COMPLAINT

Plaintiff Alkem Laboratories Limited ("Alkem"), by and through its attorneys, Winston & Strawn LLP, brings this Complaint against Defendant NPS Pharmaceuticals, Inc. ("NPS") and alleges as follows:

THE PARTIES

1. Alkem is an Indian company having a place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

2. On information and belief, NPS Pharmaceuticals, Inc. is a company organized and existing under the laws of the State of Delaware, having a place of business at 550 Hills Drive, Bedminster, New Jersey 07921. On information and belief, NPS has a regular and established place of business in this District.

JURISDICTION AND VENUE

3. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code.

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337, 1338(a), 2201, and 2202.

5. NPS is subject to personal jurisdiction in this judicial district. On information and belief, NPS sells or distributes a substantial volume of its pharmaceutical products and regularly conducts business in the State of Illinois and in this District, through sales of pharmaceutical products including Gattex and Natpara, among others. On information and belief, NPS markets and provides information about its pharmaceutical products to practitioners in this State and this judicial district. On information and belief, NPS's pharmaceutical products are prescribed to patients in this State and this judicial district.

6. On information and belief, NPS has established continuous and systematic contacts with this State and this judicial district and has purposefully availed itself of the benefits of jurisdiction in this State and this juridical district. NPS has a presence in this State and District because it has a registered agent here, CT Corporation, located at 208 S. LaSalle Street, Suite 814.

7. By not granting a covenant not to sue to Alkem, NPS has taken steps to prevent the launch of generic drug products in this State and District, leading to a foreseeable harm to the public.

8. On information and belief, NPS executives and management have entered this District for business purposes, including to negotiate publicly touted agreements with Takeda Pharmaceuticals and Abbott Laboratories, both located in this District.

9. On information and belief, NPS pharmaceuticals has established a place of business in this District, as shown by recent advertising job opportunities for positions in

Chicago, including the position of "Patient Advocacy Liaison – Central Region" which position will be located in Chicago.

10. By statute, 21 USC § 355(j)(5)(c), "A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business."

11. By virtue of NPS's actions within and directed to this District, NPS has established a permanent and continuous presence here and is subject to personal jurisdiction here.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 and in that NPS has done and is currently doing business in this State and this judicial district. Venue is also proper because the subject matter of this litigation stems from the notice letters sent by Alkem to NPS, with such notice letters identifying counsel located in this District as the registered agent for communications with Alkem, an entity in the country of India.

BACKGROUND

13. The United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 6,071,970 ("the '970 patent") on June 6, 2000, naming NPS as the assignee on the face of the patent.

14. Upon information and belief, Janssen holds approved New Drug Application ("NDA") No. 022304 for tapentadol immediate-release oral tablets of 50 mg, 75 mg, and 100 mg. These products are marketed by Janssen under the proprietary name NUCYNTA®.

15. Upon information and belief, Janssen holds approved NDA No. 200533 for tapentadol extended-release tablets of 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg. These products are marketed by Janssen under the proprietary name NUCYNTA ER®.

16. In connection with an NDA, a company like Janssen may include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2). The NDA holder can apparently list patents that it does not own.

17. On request from an NDA holder, the FDA automatically lists the NDA holder's disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "*Orange Book*." The FDA does not evaluate whether the claims of the disclosed patents actually cover the drug or method of using such drug, or whether the patent is valid; its actions are "purely ministerial." *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002).

18. Although Janssen is the NDA holder for NUCYNTA and NUCYNTA ER, the NPS '970 patent is listed in the *Orange Book* in connection with NDA Nos. 022304 and 200533.

19. Alkem filed ANDA No. 205015 seeking FDA approval to market its generic version of tapentadol immediate-release oral tablets of 50 mg, 75 mg, and 100 mg ("Alkem's generic immediate-release products") and made reference to NDA No. 022304. As part of Alkem's ANDA, Alkem submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), commonly called a "paragraph IV certification," that the '970 patent is invalid, unenforceable, and/or not infringed by Alkem's generic immediate-release products.

20. Alkem also filed ANDA No. 205016 seeking FDA approval to market its generic version of tapentadol extended-release oral tablets of 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg ("Alkem's generic extended-release products") and made reference to NDA No. 200533. As

part of Alkem's ANDA, Alkem submitted a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), that the '970 patent is invalid, unenforceable, and/or not infringed by Alkem's generic immediate-release products.

21. On June 19, 2013, Alkem sent a letter to NPS notifying it that Alkem had submitted ANDA No. 205015 for tapentadol immediate-release tablets and that the ANDA contained a paragraph IV certification that the '970 patent is invalid, unenforceable, and/or not infringed by its proposed generic products.

22. On June 28, 2013, Alkem sent a letter to NPS notifying it that Alkem had submitted ANDA No. 205016 for tapentadol extended-release tablets and that the ANDA contained a paragraph IV certification that the '970 patent is invalid, unenforceable, and/or not infringed by its proposed generic products.

23. Alkem's June 19 and June 28 notice letters contained an offer of confidential access to relevant portions of ANDA Nos. 205015 and 205016 to NPS so that it could obtain more information if desired to determine whether Alkem's generic products would infringe any valid claim of the *Orange Book*-listed patents, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

24. On information and belief, NPS received the June 19 notice letter on June 20, 2013.

25. On information and belief, NPS received the June 28 notice letter on or before July 1, 2013.

26. Alkem's June 19 and June 28 notice letters initiated a 45-day statutory period during which NPS had the opportunity to file an action for patent infringement. NPS elected not to sue Alkem within that 45-day period, therefore granting Alkem the right to have any patent dispute resolved.

27. More than 45 days have passed since Alkem sent its notice letters to NPS and NPS received the notice letters, yet NPS has not alleged infringement of the '970 patent against Alkem. Alkem requested a covenant not to sue on the '970 patent, to resolve any patent dispute since NPS chose not to sue Alkem on the patent, but was unable to reach an agreement with NPS. There is no covenant at this time, nor any other assurances about the ability of Alkem to offer its generic immediate-release and extended-release drug products free and clear of the '970 patent. Thus, there exists an ongoing and ripe dispute because of the threat of suit pursuant to the '970 patent. This ongoing and ripe dispute necessitates the filing of this complaint.

28. In the notice letters, NPS was offered confidential access to ANDA Nos. 205015 and 205016. The 45-day period for NPS to file suit having expired, with no patent infringement suit filed against Alkem regarding the '970 patent, Alkem now has the statutory right to resolve any patent dispute. Pursuant to 21 U.S.C. § 355(j)(5)(C)(1)(II) and 35 U.S.C. § 271(e)(5), there is now an actual and justiciable controversy between Alkem and NPS as to whether the '970 patent is invalid or will not be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Alkem's generic immediate-release or extended-release drug products.

29. The '970 is listed in the *Orange Book* in relation to NDA Nos. 022304 and 200533, and Alkem filed its Paragraph IV certification for the '970 patent. Thus, a justiciable controversy between Alkem and NPS exists regarding whether Alkem's generic immediate-release or extended-release drug products will infringe any valid and enforceable claims of the '970 patent.

COUNT 1: PATENT NON-INFRINGEMENT/INVALIDITY AS TO ANDA NO. 205015

30. Alkem re-alleges and incorporates the allegations of paragraphs 1-29 as if fully set forth herein.

31. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the '970 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Alkem's drug products described by ANDA Nos. 205015. Alkem further seeks a declaration that the claims of the '970 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

32. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of Alkem's drug products described by ANDA Nos. 205015 will infringe any valid and enforceable claim of the '970 patent.

33. Alkem is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Alkem's drug products described by ANDA Nos. 205015 will not infringe, directly or indirectly, any valid and enforceable claim of the '970 patent, and/or that all claims are invalid.

COUNT 2: PATENT NON-INFRINGEMENT/INVALIDITY AS TO ANDA NO. 205016

34. Alkem re-alleges and incorporates the allegations of paragraphs 1-33 as if fully set forth herein.

35. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid and enforceable claim of the '970 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Alkem's drug products described by ANDA Nos. 205016. Alkem further seeks a declaration that the claims of the '970 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

36. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of Alkem's drug products described by ANDA Nos. 205016 will infringe any valid and enforceable claim of the '970 patent.

37. Alkem is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Alkem's drug products described by ANDA Nos. 205016 will not infringe, directly or indirectly, any valid and enforceable claim of the '970 patent, and/or that all claims are invalid.

ALKEM'S PRAYER FOR RELIEF

WHEREFORE, Alkem respectfully requests that the Court enter a Judgment and Order in its favor and against Plaintiffs as follows:

A. For a declaration that the manufacture, use, offer to sell, sale, and/or importation into the United States of the drug product described in Alkem's ANDA No. 20515 does not, and will not, infringe any valid and enforceable claim of the '970 patent;

B. For a declaration that the manufacture, use, offer to sell, sale, and/or importation into the United States of the drug product described in Alkem's ANDA No. 20516 does not, and will not, infringe any valid and enforceable claim of the '970 patent;

C. For a declaration that the claims of the '970 patent are invalid;

D. For a declaration that this case is exceptional in favor of Alkem and awarding attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;

E. For an award of costs and expenses; and

F. For such other relief as the Court determines to be just and proper.

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